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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,522	BENEDICT ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. D-Mannose capsules are known and have been used by the public for, *inter alia*, urinary tract infections. See D-Mannose 500 mg capsules from NOWfoods.com enclosed herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al.

The claims are drawn to a method for inhibiting conception comprising administering D-mannose to inhibit interaction between a sperm and a female egg. Administration is oral and optionally intra-vaginally and is optionally administered with another known contraceptive.

Morris et al. teach a human amniotic fluid-derived glycoprotein, glycodelin-A (GdA), which has a high mannose content, inhibits gamete binding in an established sperm-egg binding system, thus inhibiting contraception (see abstract).

It fails to teach administering D-mannose to inhibit the interaction.

It would have been obvious to administer D-mannose to inhibit contraception. Motivation to employ D-mannose would come from the teachings of the prior art wherein GdA, having a high mannose content, inhibits gamete binding. Although the prior art does not teach inhibition of conception specifically, conception is not possible when gamete binding does not occur, thus inhibiting conception.

2. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al.

The claims are drawn to a method for inhibiting contraception, comprising administration of D-Mannose.

Chen et al. teach that almost 50% of spermatozoa, which was bound to the zona (pellucida) of an egg, detached from it when d-mannosylated albumin (DMA) was introduced to the incubation medium. Chen et al. teach inhibition of fertilization in vitro. The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose causes spermatozoa to detach from the egg in vitro, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of spermatozoa-zona pellucida binding with in vitro methods as recited by Chen et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–egg binding would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be

useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

3. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornwall et al.

The claims are drawn to a method for inhibiting contraception, comprising administration of D-Mannose.

Cornwall et al. teach that D-mannose incubated with mouse spermatozoa resulted in a dose-dependent decrease in the number of spermatozoa bound per egg without a deleterious effect of sperm motility.

The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose causes a reduction in the number of spermatozoa bound per egg in vitro, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula

therein and the dosage regimen desired for the composition. Regarding the mode of administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of sperm-egg binding with in vitro methods as recited by Cornwall et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–egg binding would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

4. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al.

The claims are drawn to a method for inhibiting contraception, comprising administration of D-Mannose.

Mori et al. teach that in the presence of D-mannose, sperm penetration through the human zona pellucida was completely blocked.

The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose blocks sperm penetration through the zona pellucida, required for conception, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of sperm-egg binding with in vitro methods as recited by Mori et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–zona pellucida penetration would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically

from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

5. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida-Komiya et al.

The claims are drawn to a method for inhibiting contraception, comprising administration of D-Mannose.

Yoshida-Komiya et al. teach significantly fewer sperm were bound per egg in the presence of competitive inhibitors of mannosidase or anti-mannose binding protein. Among the sugars examined, D-mannose was the most potent inhibitor causing 70% reduction in the number of sperm bound per egg (see abstract).

The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose causes a reduction in the number of spermatozoa bound per egg in vitro, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of

administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of sperm-egg binding with in vitro methods as recited by Yoshida-Komiya et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–egg binding would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 12 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,753,319 B2. This is a double patenting rejection.

Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3 and 4 are are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/921748. This is a provisional obviousness-type double patenting rejection. The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claims 1-3 require the D-Mannose to be placed in a natural habitat of a targeted animal or in a natural food form or in a drinking supply. Instant claims 1, 3 and 4 are broadly inclusive thereof because they are drawn to inhibiting conception of a female comprising administration of D-Mannose in the form of a capsule or tablet or mixed with a food or drink. It would have been obvious to anyone of ordinary skill in the

art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
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2/17/05

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